

the safety and effectiveness of the product. Under the law, drug companies are required to do additional studies to confirm that the drug is safe, effective and works for its approved indication.

The importance of conducting postmarketing studies to ensure the safety of drugs approved through accelerated approval is illustrated by the example of encainide and flecainide. In the 1980's encainide and flecainide were approved to treat ventricular arrhythmia after myocardial infarction. Arrhythmias are a risk factor for heart attacks and encainide and flecainide are very good at suppressing arrhythmias. People assumed that because the drugs were good at suppressing arrhythmias, they would also prevent heart attacks. While this treatment was on the market between 250,000 and 500,000 people were prescribed the drug every year to prevent heart attacks. When the postmarketing clinical trial was conducted to confirm that encainide and flecainide did in fact reduce heart attacks, the study found these drugs actually tripled the rate of death. The drugs were withdrawn from the market. If the postmarketing study had never been completed, doctors would have continued to prescribe a drug that they thought was beneficial but was actually killing people.

Postmarketing studies are also important to ensure that drugs approved through accelerated approval actually work. In May 2003, Iressa, which is manufactured by AstraZeneca, was approved under the accelerated approval process for treatment of non-small cell lung cancer in individuals who have failed to respond to two or more courses of chemotherapy. Iressa showed promise in early studies. The FDA approved Iressa, on the condition that AstraZeneca continue research on the drug to confirm the early results. Complying with the FDA's mandate, AstraZeneca conducted a postmarketing study and found that, for most people, Iressa was not effective. The drug was withdrawn from the market. This trial provided critical information to both physicians and patients who are trying to determine the best course of treatment for this horrible disease. If the postmarketing study had never been completed, doctors would have continued to prescribe it and patients would have continued to spend \$1,800 a month for a drug that is ineffective for most patients when there are alternative treatments available.

Unfortunately, many companies fail to conduct the postmarketing studies they promised to complete as a condition of approval on a timely basis and the public may go years without knowing whether the drugs approved through accelerated approval are really safe and effective. According to information provided by the FDA to my staff on March 30, 2005, drug companies take a very long time before they even initiate postmarketing studies that are required as a condition of approval as of March 9, 2005; companies with outstanding trials had been selling these products to the public for an average of 1 year and 10 months and up to 6 years and 9 months without even initiating the required studies.

Despite the fact that companies often wait years before starting required postmarketing studies, the FDA has never used the only mechanism it has to enforce compliance with the requirement: withdrawal of the product. According to the HHS IG, "Currently, short of withdrawing a drug from the market—a remedy available to FDA only in limited cir-

cumstances—the only short-term, practical options available to FDA in dealing with drug applicants that do not comply with the terms of their commitments are sending letters and placing phone calls. Providing FDA reviewers with additional tools, such as the ability to impose monetary fines, may send a signal to drug applicants that there are consequences when postmarketing study commitments are not fulfilled." The SAFE Drug Act will provide additional enforcement mechanisms.

The system of tracking postmarket safety issues and monitoring and enforcing postmarketing studies is broken and failing to ensure patient safety. The SAFE Drug Act will address these problems by:

(1) Providing the FDA with authority to require postmarketing studies and enforce the prompt completion of those studies;

(2) Providing the FDA with mechanisms to help monitor the progress of postmarketing studies;

(3) Providing the Secretary with the authority to require that the label include specific wording to ensure safe and effective use of a product including special labeling to help consumers identify accelerated approved drugs or biologics until converted to full approval;

(4) Restricting direct to consumer advertising for accelerated approved drugs or biologics until converted to full approval;

(5) Providing FDA employees with enhanced whistleblower protections if they are retaliated against for reporting violations of laws or regulations or a significant threat to public health and safety to Congress, GAO, Federal Agencies, or their bosses; and

(6) Requires reports to Congress on the systems to track postmarketing safety issues and approvals that are based on Non-Inferiority Trials.

According to a recent Wall Street Journal Online/Harris Interactive health-care poll, a majority of the American public is concerned about the FDA's ability to ensure the safety and efficacy of drugs. We need to stop the erosion of public confidence in the FDA, reform the system of postmarketing studies, and ensure that FDA balances the desire to speed drugs to market with its critical role as the watchdog of public health. I urge my colleagues to support the SAFE Drug Act.

#### TRIBUTE TO RUKERT TERMINALS CORPORATION'S 85TH ANNIVERSARY

##### HON. BENJAMIN L. CARDIN

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. CARDIN. Mr. Speaker, it is with great honor that I rise today to commemorate the Rukert Terminals Corporation's 85th Anniversary. Located in Baltimore, Maryland, Rukert Terminals Corporation, which specializes in salts, metals, ores, and fertilizers, is one of the city's premier privately owned marine terminal operators.

Since its foundation in 1921 by William G. Norman or "Cap" Rukert, Rukert Terminals has been a hard-working, family owned business that has thrived due to its strong commitment to quality service. Due to the leadership of Norman Rukert and his son, Rukert Terminals has developed over the years from a sin-

gle truck and stable business to occupying more than one million square feet of storage space. Through the use of the most modern techniques, Rukert Terminals handles the nation's dry and break-bulk cargoes to ensure transfer and storage of the highest caliber. For several decades, the company has continuously provided quality jobs to the citizens of Baltimore.

The city of Baltimore is an excellent place to live, filled with hard-working, dedicated citizens. The Port of Baltimore's economic contributions have been tremendous, generating \$2 billion in revenue annually, and employing 19,000 Marylanders in direct jobs, and another 87,000 in indirect and maritime-related occupations. Rukert Terminals is part of the success of this port city, supplying superior warehousing, stevedoring, and vessel transfer services for the region.

I urge my colleagues in the U.S. House of Representatives to join me today in honoring this third generation family business, which for eighty-five years has provided quality marine services to one of America's premier cities while maintaining a standard for excellence that is a model for the rest.

#### RECOGNITION OF LIEUTENANT COLONEL KEVIN STODDARD OF THE UNITED STATES ARMY

##### HON. MELISSA L. BEAN

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Ms. BEAN. Mr. Speaker, I rise today to pay tribute to Lieutenant Colonel Kevin Stoddard of the U.S. Army who is the Program Manager for Crew Served Weapons.

Col. Stoddard has set a standard of excellence for himself and his office, constantly striving to ensure that our troops are issued the best equipment possible during the Global War on Terrorism. Though he has had many great achievements, Col. Stoddard should be recognized for his contributions to the Common Remotely Operated Weapon Station, or CROWS project.

Col. Stoddard has had the individual responsibility for ushering this innovative piece of technology out of development and into the hands of our Soldiers. His steadfast commitment to protecting the force has ensured that today's standard for Humvee convoys in Iraq and Afghanistan is a soldier operating CROWS from behind life saving armor, protected from lethal IEDs and gun fire.

Col. Stoddard used firsthand feedback from Soldiers to lead his program office and partner contractors in ensuring that the CROWS developed today is the technology soldiers want and need. His high standards of leadership and commitment to program excellence brought him to Iraq where he personally observed CROWS in combat to prove his concept and vision. Indeed, Col. Stoddard is personally responsible for saving the lives of many Soldiers currently deployed overseas.

Mr. Speaker, Col. Stoddard and CROWS have truly been a force protection success story for the Army and our soldiers. He embodies the highest tenants of leadership, acquisition reform, and the Army's innovative rapid fielding initiative and is worthy of our commendation today.

TRIBUTE TO REVEREND JAMES A. HARRIS

**HON. CHRIS VAN HOLLEN**

OF MARYLAND

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. VAN HOLLEN. Mr. Speaker, I rise today to congratulate my constituent, the Reverend James A. Harris, on his 80th birthday, which he will celebrate on August 25, 2006.

Reverend Harris has led a life of distinction and accomplishment. After growing up in Des Moines, Iowa, he served as a combat pilot with the famed Tuskegee Airmen during World War II. He went on to receive Bachelor of Fine Arts and Master of Fine Arts degrees at Drake University and later earned post-graduate degrees at Drake Divinity College, Oklahoma A&M University, and American University.

Reverend Harris's numerous accomplishments and contributions to our community include his service as the first African American male President of the National Education Association (1974–75) and as a principal in the D.C. Public School system from 1975–88. He is a lifetime educator and scholar and a lifetime member of Kappa Alpha Psi fraternity. His career as a founder and pastor of Faith Community Baptist Church in Silver Spring, Maryland has enabled him to make a difference in countless lives. Named one of the "100 Most Influential Black Americans" by Ebony Magazine in 1975, Reverend Harris has been known for his humility and service to Montgomery County, Maryland for more than 25 years. His leadership has had a tremendous impact on countless individuals throughout our community.

Mr. Speaker, I am pleased to take this opportunity to thank Reverend Harris for his many years of service to our community and to our nation. I extend my heartiest congratulations to him on the occasion of his 80th birthday, and I hope his celebrations this year and in the years to come are filled with the love and happiness of his family and friends.

**INTRODUCTION OF SURVEY OF INCOME AND PROGRAM PARTICIPATION LEGISLATION**

**HON. CAROLYN B. MALONEY**

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mrs. MALONEY. Mr. Speaker, today I, along with Senator JACK REED (D-RI) in the Senate, introduce legislation that will establish a Commission on the Survey of Income and Program Participation. The President has proposed eliminating the SIPP in his FY 2007 Budget, with a redesigned survey to take its place in 2009. This is careless, as it takes away one of the most valuable sources of data on the economic well-being of American families. The SIPP Commission represents a fair process for changing or eliminating the survey if the need arises. Should someone wish to change the SIPP, a detailed proposal outlining the change, its justification, and the timetable on which it should take place, will be submitted to the SIPP Commission for evaluation. Members of the Commission would include the Director of the Office of Management and Budget, one

appointed member from Department of Agriculture, the Department of Labor, the Department of Energy, the Department of Health and Human Services, the Social Security Administration, the Bureau of the Census, and two members from the National Academy of Sciences.

**RECOGNIZING THE SERVICE OF THE STAFF OF THE JAMES HALEY VA MEDICAL CENTER'S POLYTRAUMA REHABILITATION CENTER**

**HON. MICHAEL BILIRAKIS**

OF FLORIDA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Mr. BILIRAKIS. Mr. Speaker, the James Haley VA Medical Center, VAMC, in Tampa, FL, is one of the busiest veterans' medical facilities in the country and provides care to approximately 142,000 veterans in Central Florida. The Tampa VAMC is also home to one of four designated polytrauma rehabilitation centers in the country where the most severely injured service members are treated.

Military service personnel wounded in Iraq and Afghanistan may have serious traumatic brain injuries alone or in combination with amputation, visual impairments, orthopedic injuries, hearing disorders and mental health concerns. The unique nature of these severe multiple injuries has created the need for a blast injury program that can address the medical, psychological, rehabilitation, and prosthetic needs of these individuals.

The Tampa VAMC has been recognized as a Center of Excellence in Rehabilitation and Spinal Cord Medicine. At the Tampa Polytrauma Rehabilitation Center, a team of as many as 10 specialists assess the needs of the catastrophically injured and their families, to determine a comprehensive treatment plan which will help each person reach the highest level of physical, emotional, and social independence in the home, workplace and community. More than 2,500 outpatients and 140 inpatients have been treated at the Tampa Polytrauma Center since the program began.

Throughout my tenure in Congress, I have spent a great deal of time at the James Haley VAMC, which serves many of the veterans who reside in my congressional district. Over the years, I have been impressed by the dedication of the men and women who work at the medical center, providing quality care and services to our Nation's veterans. Dr. Steven Scott, the chief of the Physical Medicine and Rehabilitation Service, and his polytrauma team should certainly be counted among the dedicated staff of the VAMC.

The Veterans' Affairs Oversight and Investigations Subcommittee, which I chair, has visited the Tampa Polytrauma Rehabilitation Center. We had an opportunity to spend time with some of our wounded Operation Iraqi Freedom and Operation Enduring Freedom service members being treated at the Polytrauma Center. We also heard from their family members who repeatedly praised the polytrauma staff for the compassionate and professional care their loved ones were receiving.

One of the things that stood out when we visited the Tampa Polytrauma Rehabilitation

Center was the positive outlook of the patients and their families—despite everything they had already been through and the daunting road of rehabilitation that still lay ahead of them. In part, I think they were able to maintain this positive attitude because of the tremendous dedication and caring work of the Polytrauma Center staff.

Dr. Scott and his staff have also been vocal advocates for their patients, raising issues to my subcommittee's attention which have improved the quality of care and services provided to polytrauma patients.

On August 5, 2006, Dr. Scott and his staff are being recognized for their service to our Nation's wounded service members and veterans. I want to take this opportunity to extend my sincere appreciation to each of them and commend them for the tremendous service they provide to our wounded military personnel and veterans.

Members of the James Haley polytrauma team: Forest Farley, Jr., hospital director; Dr. Steven Scott, D.O., chief, Polytrauma Center; Dr. John Merritt, M.D., chief, Spinal Cord Injury; Dr. Joel Scholten, M.D.; Dr. Cecille Pope, M.D.; Dr. Gail Latlief, D.O.; Dr. Faiza Humayun, M.D.; Dr. Rebecca Kayo, Ph.D.; MAJ Steve Moten, U.S. Army, DoD Liaison; SGM Vincent Conti, U.S. Army, DoD Liaison; Carolyn Clark, public affairs officer; Barbara Darkangelo, P.T.; Judith Pink-Goldin, O.T.; Marti Veneman, R.N. and nurse manager; Nancy Kronawetter, R.N.; Diana Cronin, R.N.; Karen Meigs, R.N.; Lea Rashka, R.N.; Joann Estep, L.P.N.; Barbara Collas, L.P.N.; Patrice Thompson, L.P.N.; Annies Joy, L.P.N.; Paula O'Keefe, R.N.; Bernice Willis, R.N.; Chaplain David LeFavor; Ivan Colon, R.N.; Frank Bormet, R.N.; Debra Banks, R.N.; Elizabeth Butron, R.N.; Pamela Keckler, L.P.N.; Ryan Baker, L.P.N.; Earl Gray, N.A.; Tracey Vaness, V.R.T.; James MacAulay, V.R.T.; Laura Manore, A.A.; Deborah Studer, S.W.; Margaret Veneman, N.M.; Douglas Gephart, P.M.R. coord.; Leslie Rothman, recreational therapy; Linda Picon, S.L.P.; Laurel Adams, O.T.; Juan Jose Villeda, P.T.; Steve Klemz, S.W.; Felicia Santos, S.W.; Jeanetta Sheppard, S.W.; Diana Phillpotts, S.W.; June Demaree, S.W.; Abby Wolf, recreational therapy; Lauren Doloresco, assistant chief, nursing; Sandra Janzen, ACOS nursing service.

**INTRODUCTION OF THE PREPAREDNESS FIRST ACT**

**HON. LORETTA SANCHEZ**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 27, 2006

Ms. SANCHEZ of California. Mr. Speaker, America needs to be prepared. Whether for a commuter train attack, as we saw recently in India, or a hurricane, like we are still rebuilding from in New Orleans, it is clear America must get serious about all-hazards preparedness, that is preparing for all emergencies—be they natural or man-made.

Yesterday I introduced the Preparedness First Act to authorize critical grant programs that our State and local governments already depend on for all-hazards emergency preparation.

The premise of H.R. 5910 is to ensure that States and localities will have a basic level of